Exhibit #1

APR 28 2006

REX MEDICAL

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K060904

1. **Submitter's Identification:**

   Rex Medical, LP
   1100 East Hector Street, Suite 245
   Conshohocken, PA 19428

   Contact: Mr. John Leedle

   Date Summary Prepared: February 9, 2006

2. **Name of the Device:**

   Cleaner™ Rotational Thrombectomy System

3. **Predicate Device Information:**

   K031610, Cleaner™ Rotational Thrombectomy System
   K040252, Cleaner™ Rotational Thrombectomy System Kit

4. **Device Description:**

   The Rex Medical Cleaner™ Rotational Thrombectomy System is percutaneous mechanical thrombectomy device which provides an effective means to restore patency to occluded synthetic dialysis access grafts. The device is used in exactly the same manner as the predicate devices.

5. **Intended Use:**

   The Cleaner™ Rotational Thrombectomy System is designed for mechanical declotting of synthetic dialysis access grafts.

6. Comparison to Predicate Devices:

The Cleaner™ Rotational Thrombectomy System is identical to the predicate Cleaner™ Rotational Thrombectomy Systems with some design improvements added to the rotational guidewire. A flexible safety core was added to the inside of the rotational guidewire and a lubricious coating was added over the macerating element.

7. Discussion of Non-Clinical Tests Performed:

All testing performed on the Cleaner™ Rotational Thrombectomy System was derived from the risk assessment which evaluated the safety and effectiveness of the design changes to the guidewire. Test methodology and acceptance criteria were derived from within Rex Medical and from related ISO standards for evaluation of this device.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The subject device, Cleaner™ Rotational Thrombectomy System, has identical indications for use as the predicate Cleaner™ Rotational Thrombectomy Systems (K040252 and K031610). The verification testing contained in our submission demonstrates that there are no differences in their technological characteristics due to the device modification, thereby not raising any new issues of safety or effectiveness. The Cleaner™ Rotational Thrombectomy System is therefore substantially equivalent to the predicate Cleaner™ Rotational Thrombectomy Systems (K040252 and K031610).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

Rex Medical
c/o Ms. Susan Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd.
Suite 200
Great Neck, NY 11021

Re: K060904
Trade Name: Rex Medical Cleaner™ Rotational System
Regulation Number: 21CFR §870.4875
Regulation Name: Thrombectomy Catheter
Regulatory Class: II (two)
Product Code: MCW
Dated: February 9, 2006
Received: April 03, 2006

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Richmond

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

Indications for Use

510(k) Number (if known): K060904

Device Name: Cleaner™ Rotational Thrombectomy System

Indications For Use:

The Rex Medical Cleaner™ Rotational Thrombectomy System is designed for mechanical declotting of synthetic dialysis access grafts.

Prescription Use _ X___ (Per 21 CFR 801 Subpart D) OR **Over-The Counter Use**_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060904